DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	6/9/2025-6/12/2025
	FEI NUMBER 3028170589

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Avtandil G. Chogovadze, Laboratory Director	
FIRM NAME Seattle Sperm Bank	STREET ADDRESS 1601 E 19th Ave Ste 4500
CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80218-1289	TYPE ESTABLISHMENT INSPECTED Reproductive Firm

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

HCT/Ps from ineligible donors which were made available for limited use were not prominently labeled with the Biohazard legend and a statement warning of communicable disease risks.

Specifically, your firm did not label all ineligible directed donors with the following warning statement, "WARNING: Advise recipient of communicable disease risks" and the biohazard legend when shipping the vials to your main storage facility.

Since February 2024, your firm has shipped approximately (b) (4) vials from directed donors to (b) (4) (b) (4) location.

OBSERVATION 2

After completion of the donor-eligibility determination, HCT/Ps were not accompanied with the summary of the records used to make the donor-eligibility determination.

Specifically, when shipping vials of donated semen from ineligible directed donors, your firm does not include a summary of record with the following documented information:

1. The reason for ineligibility.
2. A statement that the communicable disease testing was performed by a laboratory.
3. The name and address of the establishment that made the donor eligibility determination.

Since February 2024, your firm has shipped approximately (b) (4) vials from directed donors to (b) (4) (b) (4) location.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Emily B Camire, Investigator		DATE ISSUED 6/12/2025

Emily B Camire
Investigator
Signed By: EMILY B. CAMIRE -S
Date Signed: 06-12-2025
09:37:16

X

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Avtandil G. Chogovadze, Laboratory Director

FIRM NAME	STREET ADDRESS
Seattle Sperm Bank	1601 E 19th Ave Ste 4500
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Denver, CO 80218-1289	Reproductive Firm

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Emily B Camire, Investigator

X Emily B Camire
Investigator
Signed By: EMILY B. CAMIRE -S
Date Signed: 06-12-2025
09:37:10

DATE ISSUED
6/12/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."